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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,338	11/26/2003	Sui Xiong Cai	1735.0350004/RWE/RAS	8374
26111	7590	09/27/2006	EXAMINER	
STERNE, KESSLER, GOLDSTEIN & FOX PLLC 1100 NEW YORK AVENUE, N.W. WASHINGTON, DC 20005			AULAKH, CHARANJIT	
			ART UNIT	PAPER NUMBER

1625

DATE MAILED: 09/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TX

<b>Office Action Summary</b>	<b>Application No.</b> 10/721,338	<b>Applicant(s)</b> CAI ET AL.	
	<b>Examiner</b> Charanjit S. Aulakh	<b>Art Unit</b> 1625	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-23, 31, 33-35 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23, 31, 33-35 and 39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

### **DETAILED ACTION**

1. The petition filed on April 28, 2004 to delete names of inventors, Eckard Weber, Gordon B. Mills and Douglas R. Green from the inventive entity has been granted and their names have now been deleted.
2. According to a preliminary amendment filed on Nov. 26, 2003, the applicants have canceled claims 24-30, 32, 36-38 and 40-83 and furthermore, have amended claims 33-35.
3. Claims 1-23, 31, 33-35 and 39 are now pending in the application.

### ***Election/Restrictions***

4. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-10, 31, 33-35 and 39, drawn to compounds of formula (I) where Y represents valine, R3 represents alkyl or saturated/unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 562, subclass 512.
  - II. Claims 1-6, 31, 33-35 and 39, drawn to compounds of formula (I) where Y represents valine and R3 represents heterocyclic or heteroaryl ring, Pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 540, subclass 450.

- III. Claims 1-4, 31, 33-35 and 39, drawn to compounds of formula (I) where Y represents valine, X represents NR<sub>4</sub> and R<sub>3</sub> and R<sub>4</sub> together form a heterocyclic or heteroaryl ring, Pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 242.
- IV. Claims 1-4, 11-16, 31, 33-35 and 39, drawn to compounds of formula (I) where Y represents valine and R<sub>3</sub>-X-C(O) represents an antioxidant or fluorescent group, Pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 549, subclass 273.
- V. Claims 17-23, 31, 33-35 and 39, drawn to compounds of formula II where Y represents valine, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 339.
- VI. Claims 1-10, 31, 33-35 and 39, drawn to compounds of formula (I) where Y represents an amino acid other than valine, R<sub>3</sub> represents alkyl or saturated/unsaturated carbocyclic ring, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 562, subclass 1+.

VII. Claims 1-6, 31, 33-35 and 39, drawn to compounds of formula (I) where Y represents an amino acid other than valine and R3 represents heterocyclic or heteroaryl ring, Pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 540, subclass 1+.

VIII. Claims 1-4, 31, 33-35 and 39, drawn to compounds of formula (I) where Y represents an amino acid other than valine, X represents NR4 and R3 and R4 together form a heterocyclic or heteroaryl ring, Pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 544, subclass 1+.

IX. Claims 1-4, 11, 12, 14, 15, 31, 33-35 and 39, drawn to compounds of formula (I) where Y represents an amino acid other than valine and R3-X-C(O) represents an antioxidant or fluorescent group, Pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 549, subclass 1+.

X. Claims 17-23, 31, 33-35 and 39, drawn to compounds of formula II where Y represents an amino acid other than valine, pharmaceutical compositions containing these compounds and a method of using these compounds, classified in class 546, subclass 1+.

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5. The inventions I through X as defined above are patentably distinct, each from the other since they are structurally so divergent that a reference showing compounds of invention I would not render compounds of inventions II through X prima facie obvious. Search required for e.g ; compounds of invention I in class 562, subclass 512 is not the same search required for e.g ; compounds of invention II in class 540, subclass 450 and therefore, constitutes a burdensome search.

6. A telephone call was made to the applicant's attorney, Mr. Robert A. Schwartzman on Sep. 15, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. If applicants elect any one of groups, VI to X, they must specify the value of amino acid ( variable Y ).

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

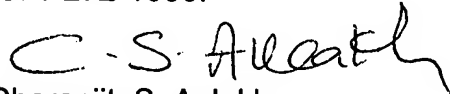
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charanjit S. Aulakh  
Primary Examiner  
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